IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

ABBOTT LABORATORIES, an Illinois corporation, and LABORATOIRES FOURNIER S.A., a French corporation, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., a Delaware corporation, Defendants.	Case No. 1:08-cv-01243 Judge Grady Magistrate Judge Denlow

DEFENDANT TEVA PHARMACEUTICALS USA, INC.'S REPLY TO PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO TEVA'S MOTION TO TRANSFER VENUE PURSUANT TO 28 U.S.C. § 1404(a) IN LIEU OF ANSWERING

I. PRELIMINARY STATEMENT

The current action and the New Jersey Action arose out of the same act, the Defendant's, Teva Pharmaceuticals USA, Inc. (hereinafter "Teva"), submission of ANDA No. 90-069 ("Teva's ANDA") to the FDA under § 505(j) of the FFDCA seeking approval to engage in the commercial manufacture, use, and sale of Fenofibrate Tablets, 145 mg ("Teva's Proposed Tablets") before expiration of all the patents listed in the Orange Book (D.I. No. 1, ¶ 15; D.I. 22, Ex. 11, ¶ 14). Teva has moved to transfer the current action to the District of New Jersey, where it can be consolidated with the related pending litigation. Plaintiffs, Abbott Laboratories and Laboratoires Fournier S.A. (hereinafter "Abbott"), have opposed transfer. (D.I. 31).

The same ANDA is at issue in both this action and the New Jersey Action; the same product is at issue; and the Stamm patents at issue here and the Elan patents at issue in New Jersey require overlapping proof of particulate fenofibrate (if any), the particle size of any particulate fenofibrate, proof of the dissolution profile of fenofibrate, and proof of the composition and method of making Teva's Proposed Tablets. At least this duplicative fact-finding is not in dispute, and Abbott has pointed to no good reason why two separate federal district courts should have to endure separate trials and risk inconsistent findings on these issues. Further, Abbott has not asserted that judicial economy would be served by two separate actions and two separate trials. Accordingly, Teva's motion to transfer should be granted.

II. ARGUMENT

A. It is Undisputed that Common Questions of Fact are Raised by the Illinois and New Jersey Actions

At the heart of Teva's motion to transfer is the fact that claims of both sets of patents – the Stamm patents at issue here and the Elan patents asserted in New Jersey – call for the court to make some common factual findings. It is to avoid burdening two separate courts in making these common factual findings, and avoiding the risk of conflicting findings, that prompted Teva to file the instant motion.

While Abbott has pointed to several factors in opposing Teva's motion that it wishes the court to consider, Abbott has not denied Teva's assertion that both sets of patents require at the very least a determination of particle size and dissolution profiles. Nor has Abbott demonstrated – or even addressed – why or how litigating these and other common questions in two separate federal courts accomplishes anything other than frustrating the interest of judicial economy. Thus, the central premise of Teva's motion stands unopposed.

B. That Different Patents are Asserted in the New Jersey and Illinois Actions is Irrelevant

Abbott purports to "illustrate" the different geneses of the Stamm Patents and Elan Patents with a table. (Opposition, D.I. 31, p. 9). This table simply shows that there are different patents asserted in Illinois and New Jersey and that the inventors are different.

Of course, claim construction and validity/enforceability analyses will have to be undertaken for each of the patents, and some of these issues are separate for the respective Stamm and Elan patents. However, that there may be separate questions does not mean that two separate courts are required to resolve them. A single court can more effectively address any separate questions unique to separate patents or claims than can multiple courts, since if separate questions arise from the patents-in-suit, they will remain related through Teva's ANDA.

In other words, even if transfer of this action to New Jersey might increase the burden on the New Jersey court by virtue of any issues unique to the Stamm Patents, the overall impact on the court *system* as to those issues will be no less than neutral because this court will not have to address those issues. In actuality, the burden on the court system will be reduced because, after transfer and consolidation, there will be one trial, not two. Also, as to those issues which are common to the Stamm and Elan patents – e.g., particle size and dissolution profile – and as to the physical properties and composition of Teva's Proposed Tablets as well as the impact of Teva's method of making its product on these characteristics, transfer will plainly lessen the burden on the court system by consolidating the fact-finding mission in one tribunal.

In the absence of consolidation, the court system's process of determining just what the properties of Teva's Proposed Tablets are will be duplicated. Abbott has not addressed this concern, and transfer for purpose of consolidating these actions is appropriate to avoid the duplication of effort by both courts.

C. The Claims-In-Suit Are More Similar Than Abbott Admits

Abbott argues that there are "deep substantive differences" between the claims of the Stamm and Elan Patents. (Opposition, D.I. 31, p. 10, ¶ 1). While, of course, different patents have different claims (as do each of the Stamm patents), the Stamm and Elan Patents have considerable similarity, which will undoubtedly require overlapping proof.

Abbott attempts to bolster its presentation by showing the first claims from "example" patents in the Illinois and New Jersey actions on different pages of its memorandum. (Opposition, D.I. 31, p. 10 & 11). This is an "apples and oranges" comparison: one relates to dissolution and the other to particle size. However, Abbott cannot dispute that both sets of patents require proof of particle size and dissolution profile, which is one prime reason noted in Teva's opening brief for transfer and consolidation. (See, e.g., D.I. 21, p. 14). Yet Abbott's brief simply ignores this issue.

A fairer understanding of the similarity of the Stamm and Elan claims is revealed by a side-by-side comparison of particle size and dissolution claims asserted in Illinois and New Jersey. For example, a side-by-side comparison of exemplary particle size claims:

Illinois Action /Stamm Patents	New Jersey Action /Elan Patents
'405 Patent, Claim 4: The composition according to claim 1, wherein the micronized fenofibrate have (sic) a size less than or equal to 20 μm.	'249 patent , Claim 1: A stable fenofibrate composition for oral administration comprising: (a) particles of fenofibrate having a D50 particle size of less than about 500 nm,....

Thus, the Plaintiffs in both actions will have the burden of offering proofs of the fenofibrate particle size, if any, in Teva's Proposed Tablets.

Similarly, when viewed side-by-side, the dissolution claims in the Stamm and Elan Patents are quite similar. For example:

Illinois Action /Stamm Patents	New Jersey Action /Elan Patents
'405 Patent, Claim 1: A composition comprising a hydrosoluble carrier and micronized fenofibrate having a dissolution of at least 10% in 5 minutes, 20% in 10 minutes, 50% in 20 minutes and *75% in 30 minutes*, as measured using the rotating blade method at 75 rpm according to the European Pharmacopoeia, in a dissolution medium constituted by water with 2% by weight polysorbate 80 or with 0.025 M sodium lauryl sulfate. (emphasis added)	'249 patent Claim 39: The [fenofibrate] composition of claim 1, wherein: (a) within about 5 minutes at least about 30% of the composition is dissolved; (b) within about 10 minutes at least about 70% of the composition is dissolved; and (c) within about 20 minutes at least about 90% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution. (emphasis added)

Abbott contends that the dissolution claims of the Stamm and Elan Patents are "different in scope (*e.g.*, requiring different percent dissolved at different times)." (Opposition, D.I. 31, p. 10, f.n. 6). While it is true that the Elan Patents may require a more rapid dissolution, Abbott's argument is irrelevant and merely sidesteps the issue. It is plain that the adjudication of infringement of both the Stamm patents and the Elan patents will, without question, entail fact-finding as to how much fenofibrate from Teva's proposed products becomes dissolved at the time points specified in both the Stamm and Elan patents: 5, 10, and 20 minutes. The overlap on this point is plain.

D. Transfer of the Action will Avoid the Duplication of Fact Finding

Abbott asserts that Teva's motion rests on the "flawed premise" that this action and the New Jersey Action are "similar." (Opposition, D.I. 31, p. 7, ¶ 1). Further, Abbott alleges that the "patents in the two actions relate to different inventions and will require different evidence." (Opposition, D.I. 31, p. 2, ¶ 2). On the contrary, while there may well be different evidence on some issues, it is unmistakable that with regard to particle size and dissolution, the Stamm and Elan Patents will require quite similar evidence. It is very possible that the same experiments could produce relevant data for the Court's infringement analyses of both the Stamm and the Elan Patents.

Consolidated or not, the assertion of the Stamm and Elan Patents will require the plaintiffs to develop evidence of infringement. *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997). This evidence, for both the Stamm patents and the Elan patents, must include proof that the fenofibrate in Teva's Proposed Tablets is particulate (which Teva disputes). If there is particulate fenofibrate in Teva's Proposed Tablets, the plaintiffs' evidence must establish what the particle size of the fenofibrate is. Given that particulate matter typically exhibits a range of particle sizes, the Court's assessment of this evidence in connection with its fact-finding concerning what the particle size (if any) of fenofibrate in Teva's Proposed Tablets is may be a complicated endeavor.

Also, for both the Stamm patents and the Elan patents, plaintiffs must introduce evidence demonstrating the dissolution profile of Teva's Proposed Tablets. Dissolution testing is a complicated procedure, requiring multiplicate tests, which produces an average value and potential outlier values at the measured time-points (e.g., 5 minutes, 10 minutes, etc.). The evidence concerning the dissolution testing may be the same in each action, and, given its

complexity, Teva may challenge the veracity of the testing protocol or the experts that plaintiffs rely on for such testing.

From the foregoing, fact-finding related to the determination of infringement of both the Stamm patents and the Elan patents will require a determination of (a) whether there is particulate fenofibrate in Teva's Proposed Tablets (b) if the fenofibrate is particulate, what is its particle size, and (c) what is the dissolution profile of fenofibrate in Teva's Proposed Tablets. Further, to address whether Teva's Proposed Tablets have particulate fenofibrate, a court must also consider Teva's manufacturing process and make factual findings relating to the structure of Teva's Proposed Tablets. Each of these issues can be expected to require assessment of highly technical information involving the testimony and cross-examination of technical experts. Merely because Abbott decided to file this action in Illinois is not a sufficient reason for two separate courts to be tasked with making factual findings on these issues.

The duplication of the fact-finding related to these issues common to the Stamm and Elan patents is not necessary, and it can and should be avoided. Since consolidation requires transfer, the consideration of judicial economy heavily favors granting Teva's motion. Indeed, this Court's policy is to grant motions to transfer for the purposes of consolidation in just this sort of situation. *Keppen v. Burlington N. R.R. Co.,* 749 F. Supp. 181, 183-84 (N.D. Ill. 1990) (recognizing the "strong policy" in favor of transferring a case to the district where a related action is pending); *Abbott Lab. v. Selfcare, Inc.*, No. 98 C 7102, 1999 WL 162805, at *2 (N.D. Ill. Mar 15, 1999) (maintaining two actions involving similar complex factual questions that will require the expenditure of considerable time and effort, even if the actions are directed to different patents, undermines judicial economy) (D.I. 22, Ex. 15).

E. Transfer of the Action will Avoid the Possibility of Inconsistent Findings

At the very least, two separate actions makes conflicting factual findings possible. This disfavored outcome is not at all improbable in a case such as this, given the highly technical nature of the fact-finding required in this patent infringement setting. It is entirely reasonable to envision that two different courts, having sat through two different proceedings and heard testimony and cross-examination of technical experts on these complicated matters on different days may reach inconsistent conclusions concerning the existence of particulate fenofibrate in Teva's Proposed Tablets, the particle size of any particulate fenofibrate in Teva's Proposed Tablets, and/or the dissolution profile of Teva's Proposed Tablets.

It is plain that, should Teva's motion be granted and the actions consolidated, there will be no possibility for inconsistent fact-finding because a common tribunal will hear all evidence relating to the common questions. This fact alone – which Abbott has not denied – demonstrates that transfer of this action will further the interest of judicial economy. The policy of this Court is to guard against the possibility of inconsistent fact-finding through transfer for the purpose of consolidation with related litigation pending elsewhere. See, e.g., *Abbott Lab.*, No. 98 C 7102, 1999 WL 162805 at *2 ("we do not wish to risk conflicting rulings"); *Bankers Leasing Ass'n, Inc. v. Lambert*, No. 88 C 7623, 1989 WL 134299, at *1 (N.D. Ill. Oct 13, 1989) (The consolidation of similar cases furthers the efficient administration of the courts, in part, by preventing the possibility of inconsistent findings in different courts) (Exhibit (Ex.) 21).

F. Transfer of the Action will Avoid the Unnecessary Complication of the Appeals Process

In deciding Teva's motion to transfer, the impact on judicial economy should be considered in view of its cost to the judicial system as a whole; and the analysis should not

neglect the potential burden on the appellate court. Accordingly, eliminating the burden of unnecessary appeals furthers the interests of judicial economy. *Cf. Crumpacker v. Crumpacker,* 516 F. Supp. 292, 296 (N.D. Ind. 1981) (noting, in the context of a motion under FED. R.CIV.P. 60(b), that eliminating unnecessary appeals furthers the interest of judicial economy).

It cannot be denied that the existence of separate actions in separate district courts could lead to separate appeals to the Federal Circuit Court of Appeals. Conversely, consolidating the infringement actions relating to the Stamm and Elan patents in a single forum, as Teva requests, will eliminate any risk of multiple appeals because a single final judgment would be reached as to all asserted patents. This alone also demonstrates that transfer for purposes of consolidation will further the interest of judicial economy, whereas litigating separate actions relating to Teva's ANDA will instead frustrate that interest.

Moreover, if, after holding separate trials, this Court and the District of New Jersey were to reach conflicting findings of fact, such will only magnify the complexity of the separate appeals, further increasing the toll on the judicial system. In addition, separate trials could lead to wasteful separate and, essentially, piecemeal appeals. To simplify any potential appellate review of litigation involving the infringement questions posed by Teva's ANDA, transfer of this action for consolidation with the New Jersey Action is all-the-more warranted. *Id.*

G. The Plaintiffs' Choice Of Venue Should Be Given No Deference Because It Was Not Based On Issues Relevant To The Asserted Patent Claims

Abbott's choice of forum should be accorded little or no deference because this forum has no connection to the material events relevant to Abbott's cause of action. See, e.g., *Amorose v. C.H. Robinson Worldwide, Inc.*, 521 F. Supp. 2d 731, 735 (N.D. Ill. 2007) citing *Chicago, Rock Island & Pac. R.R. Co. v. Igoe*, 220 F.2d 299, 304 (7th Cir. 1955). Abbott has not disputed Teva's assertion that the Stamm Patents were not invented in Illinois nor that its product is not

manufactured in Illinois (Teva's Memorandum, D.I. 21, pp. 11-12). Instead Abbott obliquely refers to "numerous, principled" reasons for choosing this forum, such as Illinois being the site of the preparation of Abbott's NDA for TRICOR®, certain meetings with Fournier within this District, and Illinois being TRICOR's® entry-point into the U.S. market. (Opposition, D.I. 31, p. 13). None of these "reasons" is relevant to Abbott's claims of infringement or the validity of the asserted patents, however, and none bears on the resolution of Teva's motion to transfer.

That Abbott's NDA for TRICOR® may have been prepared in Illinois, and that Illinois may be the point-of-entry for TRICOR® into the U.S. market is not at all relevant. This action dose not concern Abbott's NDA or Tricor's point-of-entry. Rather, the cause of action arises out of Teva's ANDA and Teva's Proposed Tablets.

Next, Abbott points to numerous trips by Fournier to Abbott within this district. However, this action arises not out of any such visits; this is a patent infringement action arising out of Teva's ANDA (see 35 U.S.C. § 271(e)(2)). As noted in Teva's opening brief (D.I. 21, pp. 10-11), the ANDA has no connection with Illinois but was instead prepared in Pennsylvania, within the jurisdiction of the District of New Jersey. Abbott has not disputed this.

Abbott also has stated that Illinois is the site of the license agreement between Abbott and Fournier involving the Stamm patents. However, this is not a contract action involving the license agreement, nor does this action in any other way arise out of that agreement. Indeed, Abbott previously asserted the Stamm patents against Teva in Delaware despite the same license agreement having this purported connection to Illinois.

Abbott also has noted that the inventors of the Stamm and Elan patents are different. However, it remains undisputed that not one of these individuals has any connection to Illinois.

Finally Abbott actually alleges that it will be "harmed" in this District should Teva prevail, and that this somehow warrants litigating here. Yet, what Abbott calls "harm" is merely the end of an improper monopoly that Abbott maintains on fenofibrate pharmaceuticals in this country should Teva prevail in the action. It is hard to justify how there can be any "harm" if Teva is able to secure American consumers' access to a legitimate generic alternative to one of Abbott's products. Nevertheless, Abbott will be equally "harmed" by the New Jersey Action because Abbott has listed the Elan patents at issue in New Jersey in the FDA's Orange Book in connection with Abbott's TRICOR® product, just as Abbott has listed the Stamm patents at issue here in the FDA's Orange Book in connection with TRICOR®. In short, Abbott will feel the economic impact of the New Jersey Action in any event; transferring this action to be consolidated with the New Jersey Action will not in any way magnify any impact to Abbott. Thus, while Teva denies that Abbott would suffer any "harm" regardless of the outcome of this action, the effect on Abbott will be equal regardless of the location of the forum.

It should not be forgotten that Abbott had the choice of litigating the Stamm patents in this district previously, when Teva moved to transfer the previous Delaware Action involving the Stamm patents and also the "Curtet" patent to this district because this Court had previously construed the Curtet patent, which also was then at issue in the previous Delaware action.[1] Abbott argued in favor of keeping that action in Delaware despite many of the same issues it now points to for opposing Teva's instant motion. Abbott's prior action in arguing for litigating these patents outside of Illinois certainly reveals that any of its purported connections to Illinois

[1] The Curtet patent is not at issue in this action, but it was asserted in the Delaware Action. However, because this Court had previously addressed the Curtet patent, *Abbott Lab. v. Novopharm Ltd.*, Nos. 00 C 2141, 00 C 5094, 01 C 19142002, 2002 WL 433584, at *8-9 (N.D. Ill. March 20, 2002) (Ex. 22), Teva had sought to transfer the Delaware action to this District.

are insufficient here for the Court to deny Teva's request for transfer of this action to New Jersey, where it can be consolidated with unquestionably related pending litigation.

III. CONCLUSION

For the reasons set forth herein and in Teva's Memorandum of Law, D.I. 21, Teva requests that, in the interest of justice and judicial economy, the Court grant Teva's motion under 28 U.S.C. § 1404(a), and order the transfer of this cause of action to the District of New Jersey.

Respectfully submitted,

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